

REMARKS

Applicant has amended claims 1, 36, 43, 78, 85, and 120, and added new claims 127-147 to further define applicant's claimed invention. Support for the amendments to claims 1, 43, and 85 may be found, for example, in Figs. 2A, 2B, and 10. Support for new claims 127-129 may be found, for example, in Fig. 2B. Support for new independent claims 130 and 139 may be found, for example, on page 5, lines 8-13 and page 8, lines 2-4 of the specification. Applicant also amended the specification to provide antecedent basis for the subject matter of originally filed claim 42 and to correct some minor informalities. No new matter has been added. It is submitted that claims 1-147 are patentable over the art of record.

In the Office Action the Examiner objected to claim 36 for lacking antecedent basis for the phrase "fusion promoting material." Applicant amended claim 36 to depend from claim 33.

The Examiner rejected claims 1-22, 25-35, 43-63, 66-77, 85-106, and 109-119 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,277,149 to Boyle et al. Applicant has amended independent claims 1, 43, and 85 to recite that the trailing end is at least in part curved along a portion of the perimeter of the body. Boyle '149 does not teach an implant having both a leading end having a generally straight portion along a portion of the perimeter and a trailing end that is at least in part curved along a portion of the perimeter of the body as now claimed.

The Examiner also rejected claims 36-42, 72, 78-84, and 120-126 under 35 U.S.C. § 103(a) as being unpatentable over Boyle '149; and rejected claims 23, 24, 64,

05-28-2002



65, 107, and 108 under 35 U.S.C. § 103(a) as being unpatentable over Boyle '149 in view of U.S. Patent No. 5,669,909 to Zdeblick et al. Applicant submits that the Examiner's rejections of these claims are rendered moot at least in view of the patentability of amended independent claims 1, 43, and 85, which Applicant submits are in condition for allowance. Thus, Applicant submits that dependent claims 23, 24, 36-42, 64, 65, 72, 78-84, 107, 108, and 120-126 are also allowable because they depend directly or indirectly from independent claims, which are believed to be allowable over the cited references.

The Examiner rejected claims 1-14, 16-19, 22, 26-32, 43-52, 55, 58, 59, 63, 66, 73, 74, 85-98, 100-102, 105, and 106 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,814,084 to Grivas et al. in view of U.S. Patent No. 4,834,757 to Brantigan. Applicant submits that independent claims 1, 43, and 85, as amended, are not taught or suggested by Grivas et al. in view of Brantigan

Applicant submits that independent claims 1, 43, and 85 are novel and non-obvious over the cited art either alone or when properly combined. Dependent claims 2-42, 44-84, and 86-129 are allowable at least due to their dependency from allowable independent claims 1, 43, or 85, or claims dependent therefrom.

As to the Examiner's request for a list of all co-pending applications, the Examiner's attention is drawn to Applicant's pending U.S. Application Nos. 10/112,746 and 10/112,745, and U.S. Patent No. 6,350,283 and its continuation application No. 09/941,425. Per the Examiner's request, the pending claims of the '746, '745, and '425 applications, and the '283 patent are attached.



In view of the foregoing remarks, it is respectfully submitted that the claims are patentable.

Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the amendments to the claims and the preceding comments. Issuance of a timely notice of allowance of the claims is earnestly solicited.

If there are any fees due in connection with the filing of this response, please charge our Deposit Account Number 50-1066. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the papers accompanying this response, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Attorney Docket No. 101.0078-00000 Customer No. 22882

CHANGES TO THE SPECIFICATION

Please amend the specification as follows:

Page 10, last paragraph:

-As shown in FIGs. 4, 9, and 10, in a preferred embodiment of the present invention, trailing end 104 can be machined to include openings 120, 122 for receiving bone-engaging screws 130a, 132 130b. Openings 120, 122 extend from trailing end 104 through upper and lower surfaces 106, 108, respectively, and are preferably oriented or directed toward the adjacent vertebral bodies. As shown in FIGs. 7 and 8, instead of openings 120, 122, trailing end 104 can include openings 132, 134, 136, 138, for receiving bone-engaging screws. Openings 132, 134, 136, 138 can be oriented toward upper and lower surfaces 106, 108 in an alternating manner as shown in FIG. 7. Alternatively, openings 132, 138 can be oriented toward upper surface 106 and openings 134,136 can be oriented toward lower surface 108 as shown in Figure 8, or any combination thereof. The number of openings in trailing end 104 can vary depending on the size of the implant and the number of screws desired to be utilized by the surgeon.--

Page 11, first paragraph:

-In a further embodiment of the present invention, the medulary canal 114 of bone ring implant 100 may be loaded with fusion promoting substances and/or the implant may be treated with fusion promoting substances. Such substances may include, but are not limited to, bone morphogenetic protein (BMP), genetic material coding for the production of bone, mineralizing proteins, bone or bone products, a chemical substance to inhibit scar formation, and other materials.--

PATENT Attorney Docket No. 101.0078-00000 Customer No. 22882

CHANGES TO THE CLAIMS

1. (Amended) An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone ring obtained from a major long bone of a human, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a portion of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space, said trailing end being at least in part curved along a portion of the perimeter of said body;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends; and

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.



- 36. (Amended) The implant of claim 331, wherein said fusion promoting material substance is bone morphogenetic protein.
- 43. (Amended) An interbody spinal implant made of a bone composite material for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone composite material, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a portion of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space, said trailing end being at least in part curved along a portion of the perimeter of said body;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends; and

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.



- 78. (Amended) The implant of claim <u>75</u>43, wherein said fusion promoting <u>materialsubstance</u> is bone morphogenetic protein.
- 85. (Amended) An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, sald implant comprising:

a body manufactured from a bone ring obtained from a major long bone of a human, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides therebetween, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a part of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space, said trailing end being at least in part curved along a portion of the perimeter of said body;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

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said implant being formed by the process of cutting a section of a long bone in a direction transverse to the longitudinal axis of the long bone to form at least a portion of a bone ring and machining said leading end to form said straight portion.

120. (Amended) The implant of claim <u>117</u>85, wherein said fusion promoting <u>material substance</u> is bone morphogenetic protein.